

# PATENT SPECIFICATION

(11) 1 496 737

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- (21) Application No. 24834/75 (22) Filed 10 June 1975  
 (31) Convention Application No. 2428397  
 (32) Filed 12 June 1974 in  
 (33) Federal Republic of Germany (DT)  
 (44) Complete Specification published 30 Dec. 1977  
 (51) INT CL<sup>2</sup> B65D 11/20  
 (52) Index at acceptance  
 B8C A



## (54) CAPSULE, ESPECIALLY FOR MEDICAMENTS

(71) We, R. P. SCHERER CORPORATION, a corporation organised and existing under the Laws of the State of Delaware, United States of America, of 9425 Grinnel Avenue, Detroit 13, Michigan, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to gelatin capsules, e.g., for containing medicaments.

Capsules consisting of telescopically engaging body and cap parts have been known for a long time. One known capsule comprises a cap which has an annular constriction approximately medially of the length thereof and which flares outwardly towards its open end. The capsule body is embraced by the annular construction when the parts of the capsule are fitted together. This allegedly results in a good fit of the cap on the body of the capsule.

In another known capsule, the internal surface of the cap has an annular projection and an annular groove and the external surface of the capsule body adjacent the opening therein is provided with an annular projection and an annular groove. A reliable seal between the cap and body of the capsule is allegedly ensured in that the projection and groove of one part of the capsule snap into the groove and projection of the other capsule part when these parts are pushed one into the other.

In yet another known capsule both the cap and the body of the capsule are formed with an annular constriction. When the two parts of the capsule are fitted one into the other, the convex annular bead formed on the inside of the capsule cap by the constriction therein enters the annular constriction of the capsule body.

Capsules for containing medicaments are today generally made from hard gelatin in a dipping process. In this process, properly designed pins are dipped into an aqueous solution of gelatin and are subsequently

withdrawn from the gelatin solution. When the gelatin has dried on a pin, the gelatin body is stripped from the pin and the resulting capsule part is cut to the desired length. In this practice it has been found that annular convex projections or concave recesses on the pin render the stripping of the gelatin body more difficult. Moreover, it is almost impossible to obtain an airtight seal between the cap and the rim of the body of the capsule when the capsule parts are fitted together due to the length tolerances of the capsule parts, particularly the different distances which occur between the rim and the annular recess of the capsule body. For a reliably fitting joint, the mating annular concave recesses or convex projections must interengage, and even this does not ensure an airtight seal.

The capsule parts, regardless of length tolerances due to their manufacture, should be adapted to be fitted one into the other in conjunction with the filling operation so that a reliable seal is obtained, which is not broken when the capsules are packaged, transported and subsequently treated, e.g., on sealing machines, and which is airtight.

The present invention provides a gelatin capsule comprising a body part and a cap part, the cap part telescopically engaging and closing the body part, one of said parts in the region where the parts telescopically overlap, being provided about its periphery with an annular series of toothlike projections which engage and locally deform the other of said parts to provide resistance to relative movement between said parts.

When the toothlike projections on the one part engage the opposed wall of the other part of the capsule, the elasticity of the gelatin is utilized and the opposite part of the capsule is slightly locally deformed. The compression of the toothlike projections prevents a pulling apart of the parts of the capsule in the longitudinal direction as well as rotation of said parts relative to each other.

The present invention facilitates, above

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all, the stripping of the capsule parts from the dipping pins as compared with capsule parts which have a continuous annular recess because the strippers used in this operation can better slide over the toothlike recesses in the dipping pins than over concave recesses.

Another problem has also been solved by the invention. The parts of previously known capsules tend to separate when the capsules are assembled after having been filled because the assembling of the parts results in the compression of air trapped in the capsules which tends to force the parts of the capsules apart. This obviously adversely affects the tightness of such capsules. In the capsules according to the present invention, little or no air can be compressed which would promote a separation of the parts of the capsule because when the parts of the capsule are fitted together the air can escape between the toothlike projections until the very end of the assembling operation, when airtightness is achieved.

In a preferred embodiment, the toothlike projections are provided only on the inside surface of the cap of the capsule. In this case only the dipping pins used to make the capsule caps must be provided with corresponding toothlike recesses and the cap parts can easily be stripped from the dipping pins. If the capsule bodies were provided with outwardly directed toothlike projections, the dipping pins for the capsule bodies would have to be provided with corresponding, outwardly directed toothlike projections. Although such an arrangement is within the scope of the present invention, it is more difficult in this case to make the dipping pins and to strip the capsule bodies provided with such teeth from the dipping pins.

As stated above, the caps of many of the previously known capsules were provided with an inwardly facing, annular convex projection for interengaging with the capsule body. Manufacturers possess large quantities of properly shaped dipping pins for use in the manufacture of such capsule caps having concave recesses. These dipping pins can be used to make the capsule according to the present invention if toothlike recesses are formed in the concave recesses of the dipping pins for the cap parts. Thus, according to a further feature of the invention, the toothlike projections are provided on an inwardly-directed annular convex projection of the cap.

The invention will be further described with reference to the accompanying drawings, in which:—

Figure 1 shows one embodiment of a capsule according to the present invention;

Figure 2 is a transverse sectional view taken on line A—A in Figure 1;

Figure 3 is an enlarged view showing the toothlike projections as seen from the inside of the capsule cap;

Figures 4 and 5 are transverse sectional views taken on lines B—B and C—C in Figure 3;

Figure 6 shows a modification of the capsule cap, partly broken away.

Figure 1 shows a capsule 1, which comprises a capsule body 2 and a capsule cap 3. At their open ends, the capsule cap 3 and the capsule body 2 terminate in rims 8 and 7, respectively. The closed ends of the two parts are designated 9 and 11, respectively, and are spherically shaped. Other end shapes may also be used. The capsule cap has an inside surface 5 and the capsule body has an outside surface 6.

Adjacent to the body portion B1 which is overlapped by the capsule cap 3, the latter has an annular portion B2, which is formed with inwardly directed, toothlike projections 10, the longitudinal axes of which are substantially parallel to the center line of the capsule cap 3.

When the capsule body 2 is fitted into the capsule cap 3, the rim 7 of the capsule body 2 slides past the portion B2. The capsule body 2 is pushed into the capsule cap 3 until the rim 7 engages the inside surface of the closed end 9 of the capsule cap 3. This results in an airtight peripheral seal at 12 between the rim 7 of the capsule body 2 and the inside surface 5 of the capsule cap 3. Because the capsule according to the invention has no annular concave recesses or convex projections which must interengage to seal the capsule, the length tolerances which are inevitable in the manufacture of any such capsule will not be significant. The airtight seal 12 between the capsule body 2 and the capsule cap 3 is relatively independent of the distance between the annular portion B2 of the capsule cap 3 and the rim 7 of the capsule body.

A reliable joint between the capsule cap 3 and the capsule body 2 is provided in that the toothlike projections 10 on the inside surface of the capsule cap 3 engage the outside surface 6 of the capsule body in the portion B1. It has been found that the engaging forces are sufficiently strong to prevent an accidental opening of the capsule 1 when the same is packaged and when the packaged capsules are handled. Figure 2 shows the toothlike projections 10 on the inside surface 5 of the capsule cap 3. These projections are distributed around the periphery of the inside surface of the capsule 3 and engage the outside surface 6

of the capsule body 2 so that the surface 6 is slightly deformed, as is shown in Figure 2.

As will be seen from Figure 3, each projection 10 has two oblique side walls 13, 14 which are connected by an intermediate portion 15. Alternatively, the side faces 13 and 14 could directly intersect so that there is no portion 15. The angle  $\beta$  (figure 4) between the lateral side walls 13 and 14 should be at least  $120^\circ$  and preferably at least  $150^\circ$ .

Particularly desirable results will be obtained if the angle of elevation  $\alpha$ , as is shown in Figure 5, is not in excess of  $40^\circ$ , and preferably not in excess of  $20^\circ$ .

The selected angles are so large ( $\beta$ ) and so small ( $\alpha$ ) because the slope of the sides of the teeth should be as gentle as possible so that the capsule caps can easily be stripped from the dipping pins. Besides, the use of such gently-sloped teeth eliminates the formation of air bubbles between the dipping pin and the capsule cap during the dipping operation. Any air disposed between the gently-sloped teeth can easily escape during the dipping operation.

For the same reason, spaces 16 are preferably provided between peripherally adjacent toothlike projections 10 so that there will be no sharp edges between adjacent teeth. Sharp edges render stripping of the capsule parts from the dipping pins and the escape of air more difficult. Besides, when the capsule parts are fitted together the wall material of the body parts can better locally deform to an arch formation when spaces 16 are provided to ensure a firm engagement of the toothlike projections and a reliable retention of the capsule parts in spite of the flat shape of the toothlike projections.

The toothlike projections 10 are preferably provided in a number that can be divided by four, and preferably by eight. The fewer toothlike projections used, the larger may be the width of said projections in the peripheral direction. Fewer projections will also reduce the formation of air bubbles and will facilitate the penetration of the liquid gelatin into and between the toothforming recesses of the dipping pins. The use of projections in a number which can be divided by four or eight is desirable because the recesses for forming the projections can be more readily formed in the dipping pins, which in use are fixed on pin bars, by special tools which can laterally engage the dipping pins from opposite sides in two or more successive steps the positions of which are offset by a suitable angle, e.g.,  $90^\circ$ .

It will be apparent from the above that the present invention permits the manufacture of a capsule which has a reliable joint between its cap and body

parts. It will also be apparent that an airtight seal between the capsule body and the capsule cap can be assured even if the dimensional stability of the individual capsule part does not meet particularly close tolerances. This is a particular advantage because the manufacture of the capsules is much simplified and many less rejects must be discarded than has previously been the case. The joint between the capsule body and the capsule cap is due to the engagement of the toothlike projections rather than to an interengagement of annular concave recesses and convex projections. For this reason the capsule body can always be pushed into the capsule cap to such an extent that an airtight seal is established between the rim of the capsule body and the inside surface of the cap. The toothlike projections hold the interfitting capsule parts against being pulled apart in the longitudinal direction and against relative rotation.

The expression "toothlike projections" as used herein and in the claims hereof not only includes projections which are more or less pointed or cornered like teeth but includes also projections which are rounded projections of any shape whatever.

Figure 6 shows a cap having a continuous peripheral inwardly facing convex projection 17. The toothlike projections 10 are provided on the inside of this convex projection 17.

#### WHAT WE CLAIM IS:—

1. A gelatin capsule comprising a body part and a cap part, the cap part telescopically engaging and closing the body part, one of said parts, in the region where the parts telescopically overlap, being provided about its periphery with an annular series of toothlike projections which engage and locally deform the other of said parts to provide resistance to relative movement between said parts.

2. A capsule according to claim 1, wherein said toothlike projections are provided on the inside surface of the cap part.

3. A capsule according to claim 2, wherein said cap part has an inwardly directed annular convex projection on which said toothlike projections are disposed.

4. A capsule according to any one of the preceding claims, having a number of said projections that can be divided by four, and preferably by eight.

5. A capsule according to any one of the preceding claims, wherein the body part terminates in a rim in sealing engagement with the interior surface of said cap part at

the closed end thereof to provide an airtight seal between the body part and the cap part.

- 5 6. A capsule according to any one of the preceding claims, wherein the toothlike projections have gently-sloping side walls both in the lateral and longitudinal direction of the capsule.

- 10 7. A capsule according to claim 6, wherein the angle between opposed laterally-sloping side walls of each toothlike projection is at least  $120^\circ$  and the angle of elevation of the longitudinal side walls of

each toothlike projection is not in excess of  $40^\circ$ .

8. A gelatin capsule substantially as herein described with reference to Figures 1 to 5 or Figure 6 of the accompanying drawings.

ERIC POTTER & CLARKSON,  
Chartered Patent Agents,  
Kingsway House,  
Kingsway,  
London, WC2B 6QX.

